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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/080,052

02/21/2002

Sung-Jin Kim

SJKIM-002US

6753

7590

06/12/2002

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EXAMINER

COE, SUSAN D

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,052

Applicant(s)

KIM, SUNG-JIN

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

1. Claims 1-15 are currently pending.

Claim Objections

2. Claim 11 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot refer to more than one set of claims. Claim 11 is drawn to the composition of claim 1 made by the process described in claim 3. This is improper. See MPEP § 608.01(n).

3. Claim 11 is also because of the following informalities: there are inappropriate paragraph breaks between “methanol:” and “water” in lines 6 and 7 and “chloroform:” and “methanol” in lines 12 and 13. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 is indefinite because the phrase “protecting brain cells” is considered indefinite. The phrase is indefinite because it is unclear exactly what conditions are encompassed by this phrase. Without a clear definition of what is considered to fall within the scope of this limitation, the metes and bounds of the claims are unclear.

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5. Claim 11 is indefinite because it is drawn to the composition of claim 1 made by the process described in claim 3. This is confusing because it is unclear what limitations need to be met in order to practice the invention as claimed.

In addition, the claim states that the Asiasari extracts are obtained by the "method described in claims 3 [sic]." Claim 3 is drawn to a composition made by a process; however, since claim 3 is a composition claim, it is confusing to refer to it as a method claim.

Claim 11 is also indefinite because the phrase "among these" in line 12 is confusing. It is unclear what is being referred to by "these."

6. Regarding claim 12, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

7. Claim 14 recites the limitation "said the content" in line 2. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 15 is indefinite because the claim uses improper Markush language.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,889,046.

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Applicant's claims are drawn to a composition of Asiasari radix.

US '046 teaches a composition used for alleviating or preventing stroke (see claims).

Treating stroke is considered to be encompassed by the limitation of "protecting brain cells."

The composition can be extracted from Asiasari radix (see column 4, lines 31-34). The composition can be in the form of a powder, tablet, capsule, suspension, syrup, injection, lotions, ointment or suppository (see column 6, lines 49-43). The composition can also be administered in a food. When administered in a food, the amount of the composition in food is 0.001 to 50% (see column 8, lines 10-13).

10. Claims 1-7, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,151, 450.

US '450 teaches an extract composition from Asiasari radix. The Asiasari radix is extracted with chloroform, ethyl acetate, and acetone (see column 1, lines 45-52). The extract is administered in the form of a tablet, capsule, powder, suspension, syrup, suppository, or injection (see column 3, lines 60-65). The extract is present in composition in amounts ranging from 5.0 to 30% (see Composition Examples 1-5).

US '450 does not specifically teach that their extract composition is able to improve memory or protect brain cells. However, since the composition of US '450 is the same as the claimed composition, the composition of US '450 would inherently have to function in the manner claimed by applicant if applicant's invention functions as claimed.

11. Claims 1, 3-7, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Derwent English abstract of Japanese Pat. Appl. No. 05178793 A.

JP '793 teaches an extract of Asiasari radix. The Asiasari radix is extracted with methanol, ethanol, acetone, ethyl acetate, chloroform, or ether. The extract is administered as tablets, capsules, powders, injections, or suppositories.

JP '793 does not specifically teach that their extract composition is able to improve memory or protect brain cells. However, since the composition of JP '793 is the same as the claimed composition, the composition of JP '793 would inherently have to function in the manner claimed by applicant if applicant's invention functions as claimed.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 3, 4, 6, 7, and 11-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Pat. No. 5,889,046.

US '046 does not specifically teach extracting the Asiasari radix in the manner claimed by applicant. However, applicant's claims product-by-process claims. Note that MPEP § 706.3(e) states that:

"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process

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claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972) ; In re Fessmann, 180 USPQ 324 (CCPA1974)."

Therefore, US '046 teaches an Asiasari radix extract which appears to be identical to the presently claimed extract, based on the fact that both the reference extract and the claimed extract are from the same plant source and both extracts are able to protect brain cells. Consequently, the claimed extract appears to be anticipated by the reference.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extracts as evidenced by their shared ability to protect the brain against injury.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

US '046 does not specifically teach administering the composition in the form of an oral aerosol as claimed by applicant. This form of administration is well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the reference in the form of an aerosol would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the reference in the form claimed by applicant.

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Claim Rejections - 35 USC § 103

13. Claims 1, 2, 6, and 7 rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,151,450.

As stated above, US '450 is considered to teach the claimed invention. However, US '450 does not specifically teach adding the extract in all of the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

US '450 also does not specifically teach administering the composition in the form of an oral aerosol as claimed by applicant. This form of administration is well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the reference in the form of an aerosol would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the reference in the form claimed by applicant.

14. Claims 1, 2, 6, 7, and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05178793 A.

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JP '793 teaches extracting *Asiasari radix* in methanol, then in a mixture of water and methanol, then in chloroform and methanol, then in chloroform, and then in methanol again. The extraction method of JP '793 encompasses that of claim 12 except that JP '793 does not manipulate the pH of the extract during the procedure. In addition, JP '793 uses the solvents in a slightly different order than that claimed by applicant in claim 11. The pH of an extraction procedure and slight varieties in the order of solvent usage in an extraction procedure are clearly result effective parameters that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal pH and solvent order to best achieve the desired extract. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

JP '793 does not specifically teach adding the extract in all of the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

JP '793 also does not specifically teach administering the composition in all of the forms claimed by applicant. These forms of administration are well known in the art to be acceptable

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means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the reference in the forms claimed by applicant.


15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC
June 3, 2002



LEON B. LANKFORD, JR.
PRIMARY EXAMINER